REMARKS

In the Office Action, claims 10, 11, 13-15, 18-25, 37-40, and 43-69 are rejected under 35 U.S.C. §112, first paragraph. Applicant believes that this rejection should be withdrawn at least based on the reasons set forth below.

More specifically, the Patent Office alleges that claims 10, 11, 13-15, 18-25, 37-40, and 43-69 are not enabling pursuant to §112, first paragraph. Applicant believes that the specification provides sufficient support such that one skilled in the art can practice the subject matter as presently claimed without undue experimentation.

Of the pending claims at issue, claims 10, 18, 23, 37, 43, 44, 51, 55, 57, 62, and 66 are the sole independent claims. Claims 10 recites a method of modulating pupil dilation; claim 18 recites a method for optimizing pupil diameter in dim light; claim 23 recites a method of modulating pupil dilation; claim 37 recites an ophthalmic, night vision formulation; claim 43 recites a method of reducing adverse visual effects of spherical aberrations on a human eye; claim 44 recites an ophthalmic formulation; claim 51 recites an ophthalmic, night vision formulation; claim 55 recites a method of reducing adverse visual effects of spherical aberrations on a human eye; claim 57 recites an ophthalmic formulation; claim 62 recites a method of modulating pupil dilation; and claim 66 recites an ophthalmic, night vision formulation. Each of the independent claims recite, in part, alpha 1 antagonist compounds that are capable of disrupting endogenous compounds which simulate dilator muscles of the eye, such as an imidazoline and an alkylating agent.

As further supported in the specification on page 13, the claimed invention utilizes a specific class of compounds known as alpha 1 antagonists to inhibit pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Ophthalmic formulations that include such class of alpha 1 antagonist compounds can allow improvement in quality of vision in dim light without negative clinical effects in normal lighting conditions. See, Specification, page 13, paragraph 47. Examples of alpha 1 antagonists include an imidazoline, such as phentolamine, and an alkylating agent, such as phenoxybenzamine, as further supported in the Specification, for example, on page 25 at paragraph 85.

Further, Applicant has conducted experiments that demonstrate the beneficial effects of the claimed invention. For example, Table 1 on page 27 of the specification demonstrates that four different types of alpha 1 antagonist compounds can reduce pupil diameter in darkness in increased amounts as compared to dapiprazole. In this regard, a phentolamine-based solution reduced the pupil diameter by 3.5 mm; a phenoxybenzamine-based solution reduced the pupil diameter by 2.0 mm; a prazosin-based solution reduced the pupil diameter by 1.5 mm; and a tolamine-based solution reduced the pupil diameter by 1.5 mm. See, Specification, Table 1. In Example 2, six additional specific types of alpha 1 antagonist compounds (e.g. tamsulosin, bunazosin, alfuzonsin, urapidil, ketanserin, and indoramin) are indicated to have some clinical effectiveness as well. See, Specification, page 25, paragraph 85.

Further, Applicant conducted an additional test to demonstrate the beneficial effects on vision by reducing the pupil diameter in dim light. As shown in Table 2, the glare and halo effects were reduced in addition to an improvement in depth perception by reducing the pupil diameter in dim light. See, Specification, page 28.

The Patent Office appeared to rely on page 4 of the specification in support of their position as indicated on pages 2-3 of the Office Action. Contrary to this position, Applicant believes that the specification in this part provides further guidance to one skilled in the art, thus facilitating the practice of the claimed invention. With respect to reference of the indols, the specification provides that the alpha-2 activity as represented by indols is of no clinical benefit. As previously discussed, Applicant has discovered that compositions that display alpha-1 antagonist activity can improve quality of vision in dim light without negative clinical effect in normal lighting conditions. This is consistent with the testing that was conducted by Applicant and as illustrated, for example, in Table 1 on page 27 where the compound yohimbe having alpha-2 activity displayed no effect on pupil diameter reduction in dim light. Thus, this provides further guidance to one skilled in the art that the alpha 1 antagonist activity is most predominant with respect to reducing pupil size in dim light, and thus improving quality of vision.

With respect to specific types of alpha 1 antagonist compounds, such as an alkylating agent, these types of compounds may have less of an effect on pupil size as compared to, other types of alpha 1 compounds, such as an imidazoline, and further may cause greater redness. See, specification, for example, Table 1, page 27. Again, this should provide further guidance to one skilled in the art that one type of alpha 1 antagonist may be more preferred in formulation than another and also may require an additional compound to reduce eye redness. Clearly, this added

description provides the skilled artisan with a greater frame work and understanding of the claimed invention, and thus facilitates the practice of same. Again, Applicant has indicated that at least 10 specific types of compounds having alpha 1 antagonist properties can display clinical effectiveness with respect to pupil diameter reduction in darkness (see, Specification, Table 1 and Example 2 at pages 24 and 25) and further that reduced pupil size does indeed have a beneficial effect on vision in dim light (see, Specification, Table 2 at page 28) as previously discussed.

Based on at least these reasons, Applicant believes that the specification provides sufficient support and guidance such that one skilled in the art can readily practice the claimed invention with undue experimentation. Therefore, Applicant believes that pending claims 10, 11, 13-15, 18-25, 37-40, and 45-69 satisfy the enablement requirement pursuant to 35 U.S.C. § 112, first paragraph. To the extent that claims 26 and 27 are rejected for alleged §112 reasons, Applicant believes that claims 26 and 27 should satisfy the requirements of 35 U.S.C. §112, paragraph 1 for substantially the same reasons as discussed above.

Accordingly, Applicant respectively requests that this rejection be withdrawn.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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